

## REMARKS

A final Office Action mailed November 16, 2004 has been received and carefully reviewed. Claims 1-15 and 24-42 are pending and currently rejected in the instant application. Claims 1 and 24 have been amended. Claims 16-23 were previously cancelled. Reconsideration of the application is respectfully requested in view of the amendments to the claims and the following remarks.

The rejections are summarized as follows: Claims 1, 2, 8, 15 and 24-31, 37 and 42 stand rejected under §102(e) over *Niazi* (U.S. Patent No. 6,638,268); claims 3, 4, 32, and 33 stand rejected under §103(a) over *Niazi*, as applied to claim 1 and 24 and in further view of *Schaerf* (U.S. Patent No. 5,409,469); claims 5, 6, 34, and 35 stand rejected under §103(a) over *Niazi* as applied to claims 1 and 24 and in further view of *Bowe* (U.S. Patent Publication 2001/0039413); claims 7, 9, 10, 36, 38, and 39 stand rejected under §103(a) over *Niazi* as applied to claims 1 and 24 and in further view of *Lepulu et al.* (U.S. Patent No. 6,533,770); and claims 11-14, 40 and 41 stand rejected under §103(a) over *Niazi* as applied to claims 1 and 24.

Claims 1 and 24 have been amended to clarify Applicant's claimed invention. Claims 1 and 24, as amended, are directed to a guide catheter including an outer sheath and an inner sheath disposed within the open lumen of the outer sheath. The inner sheath conforms to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assumes a pre-formed shape different from the shape of the outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath.

Applicant submits that the amendments to claims 1 and 24 provided herein should be entered, as the amendments place the case in condition for allowance. M.P.E.P. §714.12-13. Further, the proposed amendments do not present new issues requiring an additional search because previously presented claim 40 recites a catheter with inner and outer sheaths wherein the claimed shape of the inner sheath is different from that of the outer sheath. Claims 1 and 24, as amended, describe an inner sheath and an outer sheath having different shapes.

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In contrast to Applicant's invention, the catheter taught in *Niazi*, with reference to Figure 1, for example, includes an outer catheter 11 and an inner catheter 12 having a single predetermined shape. *Niazi* states, at column 4, lines 4-8 "for optimum deployment in the coronary sinus inner and outer catheters 11, 12 preferably have a predetermined shape and a certain degree of stiffness to maintain such shape during manipulation in the heart, but still flexible enough to bend when required." Figure 1 of *Niazi* illustrates the inner catheter 12 disposed within outer catheter 11 and having the same shape as outer catheter 11. *Niazi* teaches that the inner and outer catheters have the same predetermined shape. *Niazi* does not teach or suggest that the inner catheter assumes a pre-formed shape different from the shape of the outer catheter when the distal end of the inner catheter is extended beyond the distal end of the outer catheter as recited in amended claims 1 and 24.

With reference to the triple catheter system illustrated in Figures 4-6, *Niazi* states at column 6, lines 19-32, that the outer guide catheter has three bends in a manner similar to outer catheter 11 and that the inner catheter also has three bends in a manner similar to outer catheter 11. Identical specifications are provided with respect to the first, second, and third bends for both the inner and outer catheters. Thus, according to the teachings of *Niazi*, the inner and outer catheters have the same shape.

*Niazi* fails to teach a guide catheter of the type contemplated in Applicant's claims which includes an inner sheath that has a distal end with a pre-formed shape, such that the inner sheath conforms to a shape of the outer sheath when retracted, but assumes the pre-formed shape different from the shape of the outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath.

Because *Niazi* fails to teach each every element and element limitation recited in independent claims 1 and 24, these claims are not anticipated by *Niazi*. Dependent claims 2, 8, 15, and 25-31, 37 and 42 are also not anticipated by *Niazi*, as these claims recite features in addition to those recited in the claim from which they depend.

Concerning the obviousness rejections of dependent claims 3-7, 9-14, 32-36, and 38-41, and without acquiescing to the Examiner's characterization of the relied-on references as they have been applied to Applicant's claims, Applicant believes it

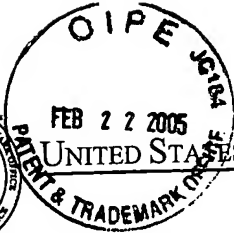
unnecessary to address all grounds for rejection of every dependent claim in view of the clear grounds for patentability of claims 1 and 24. These dependent claims include all of the limitations of claims 1 or 24, and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant, however, reserves the right to address these rejections should the Examiner maintain the rejection of the claim 1, notwithstanding Applicant's remarks presented hereinabove.

It is believed that pending claims 1-15 and 24-42, are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,  
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Date: January 18, 2005

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,911	01/07/2002	Frank E. Manning	GUID.038US01	4087

7590

02/02/2005

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EXAMINER

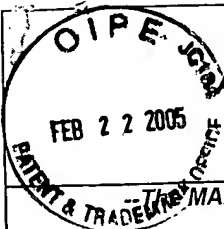
FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**COPY**



# Advisory Action

Application No.

10/041,911

Applicant(s)

MANNING ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-15 and 24-42.

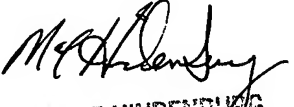
Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Continuation of 2. NOTE: Independent claims 1 and 24 as amended include the limitation "different from the shape of the outer sheath" requiring further consideration and/or search. Applicant asserts that such a limitation does not present new issues because claim 40 recites a catheter with inner and outer sheaths where the shape of the inner sheath is different from that of the outer sheath. However, claim 40 does not require the inner sheath and outer sheath to have different shapes. Additionally, assuming Applicant's assertion is correct, claims 1 - 15, 23 - 39, 41 and 42 did not include such a limitation prior to the proposed amendment.

  
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